

REMARKS

1. Preliminary Remarks

a. Status of the Claims

Claims 31, 32, and 39-42 are pending in this application. Claims 31 and 39 are allowed; and claims 32 and 40-42 are rejected. Claims 41 and 42 are amended. Applicant respectfully requests entry of the amendments and remarks made herein into the file history of the application. Upon entry of the amendments, claims 31, 32, and 39-42 will be pending and under active consideration.

b. Amendment to the Claims

Claims 41 and 42 are amended to relate to an oligonucleotide probe of 16-140 nucleotides comprising the nucleic acids of claims 31 and 32, respectively. Support for this amendment is found in the application as originally filed at paragraphs 0043-0046 and 0053. In view of the amendments finding support in the application as originally filed, Applicant submits that no new matter is added.

2. Patentability Remarks

a. 35 U.S.C. § 112, second paragraph

On pages 3 and 4 of the Office Action, the Examiner rejects claims 41 and 42 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Specifically, the Examiner asserts that the limitation “the vector” in these claims has insufficient antecedent basis. Amended claims 41 and 42 no longer recite “the vector,” thereby obviating this rejection. Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 41 and 42 under 35 U.S.C. § 112, second paragraph.

b. 35 U.S.C. § 102

On pages 4-8 of the Office Action, the Examiner rejects claims 32, 40, and 42 under 35 U.S.C. § 102(e) as allegedly being anticipated by WO 03/029459 (“Tuschl” hereafter). The Examiner asserts that Tuschl discloses a 22 nucleotide-long sequence of mouse miR-151 in Table 3, which has Tuschl SEQ ID NO: 179. The Examiner asserts that the sequence of miR-151 is 90% identical to instant SEQ ID NO: 15, having the same length and differing in sequence by only two nucleotides. The Examiner further asserts that Tuschl teaches any miRNA listed in Table 3 of Tuschl, any sequence that is 80%, 90%, 95%, or 99% identical to these miRNAs, and complements of these miRNAs. The Examiner asserts that these sequences necessarily include instantly claimed SEQ ID NO: 15 and its complement.

The Examiner also asserts that one of skill would instantly recognize each 22-nucleotide sequence that is 80% and 90% identical and complementary to miR-151 as fully as if each sequence was written out. The Examiner further asserts that the genus of sequences disclosed by Tuschl anticipates instant SEQ ID NO: 15 because the rejection is based on a single reference, the list of sequence disclosed by Tuschl is necessarily finite and defined, and the instant claims require no function. Further, the Examiner contends that Applicant has not provided evidence to show that one of skill could not have envisioned each sequence disclosed by Tuschl. Applicant respectfully disagrees.

A claim is anticipated only if each and every element of the claim is found in a single prior art reference. See MPEP § 2131, *citing Verdegaal Bros. v. Union Oil Co. of Calif.*, 814 F.2d 628 (Fed. Cir. 1987). Furthermore, a claimed compound is not anticipated by a genus when (1) it is necessary to select portions of teachings within a reference and combine them; and (2) the classes of substituents are not sufficiently limited or well delineated. See MPEP § 2131.02 *citing Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art could not at once envisage the specific compound within the generic formula, the compound is not anticipated. See *Id. citing In re Petering*, 301 F.2d 676 (CCPA 1962). A compound is at once envisaged only if one of skill could draw the structural formula or write the name of each of the compounds included in the generic formula. *Id.* For example, a generic formula does not anticipate a species included in the formula when the formula encompasses a vast number, and perhaps even an infinite number of compounds. See *Id.* Applicant submits that the genus of nucleic acids disclosed by Tuschl is the very kind that cannot anticipate the claimed species, because Tuschl teaches a vast, almost infinite number of nucleic acids.

Instant claims 32, 40, and 42 relate to a nucleic acid having SEQ ID NO: 15 and a DNA encoding this sequence, and their complements. The Examiner acknowledges that Tuschl does not specifically disclose instantly claimed SEQ ID NO: 15. Instead the rejection relies on Tuschl's alleged disclosure of miR-151 in Table 3, together with 90% variants of this sequence, and their complements. In order to set forth this reasoning, the Examiner had to select portions of teachings within Tuschl and combine them—the Examiner had to pick one specific miRNA from one specific table, and then rely on a generic disclosure of 80%, 90%, 95%, or 99% identical sequences, as well as complements. As described below, not only is the genus of species massive in and of itself, but the Examiner ignores a considerable number of additional nucleic acids disclosed by Tuschl, which increases exponentially the size of the genus of nucleic acids that this reference teaches.

Tuschl discloses an isolated nucleic acid molecule comprising a nucleotide sequence in Table 1, 2, 3, or 4. Tuschl at page 2, line 4. These tables disclose a total of 160 unique nucleic acid sequences. The sequences range from 17 to 24 nucleotides in length, as follows.

Length of sequence (n)	Number of sequences having length n
17	1
18	3
19	3
20	7
21	29
22	80
23	34
24	3

For each sequence of a particular length, the number of sequences at least 80% identical to the sequence, counting only base replacements, is as follows.

Length of sequence	Number of sequences at least 80% identical
17	19636
18	23464
19	27760
20	424996
21	522649
22	636241
23	767419
24	917911

Accordingly, the combined number of sequences at least 80% identical to each of the sequences disclosed in Tables 1-4 of Tuschl is as follows.

Length (n)	Total number of sequences at least 80% to all sequences of length n
17	19636
18	70392
19	83280
20	2974972
21	15156821
22	50899280
23	26092246
24	2753733

Thus, counting only the specific sequences disclosed in Tables 1-4 of Tuschl, and sequences at least 80% to these sequences, Tuschl discloses 98,050,360 different sequences, and 98,050,360 complements, or a total of 1.96×10^8 sequences. Assuming one of ordinary skill could write down or identify at a rate of one sequence a minute each Tuschl sequence, a sequences at least 80%

identical to each Tuschl sequence, and its respective complements, it would take approximately 2270 days and 6.21 years to identify the claimed sequences from Tuschl. Even using a computer to display each of these Tuschl sequences would require one of skill to read and analyze each sequence, and therefore would fall within the time frame of our assumption.

Not only does Tuschl disclose nearly 200 million nucleic acids, 80% variants and complements, but the Examiner has overlooked the fact that Tuschl also discloses nucleotide sequences that hybridize under stringent conditions to the nucleotide sequences shown in Tables 1-4, to their complements, and to “highly identical” sequences. Tuschl at page 2, line 15; and page 3, line 7. Further, Tuschl discloses an isolated nucleic acid molecule **comprising** the sequences in Tables 1-4, as well as 80% variants, complements, and stringently-hybridizing sequences. Tuschl at page 2, line 4. By using the open-ended term “comprising,” Tuschl discloses an even larger number of nucleic acids. Thus, the nucleic acids of Tuschl are not limited to 19-24 nucleotides in length, but can have a length of 18-100 nucleotides. Tuschl at page 3, line 14. The Examiner failed to acknowledge that any of these sequence variants are also disclosed in Tuschl, which vastly increase the number of sequences disclosed by this reference. For example, sequences capable of hybridizing to nucleic acids at least 80% identical to the sequences disclosed in Tables 1-4 drastically expands the size of the genus of sequences disclosed in Tuschl, pushing the number into the billions. Applicant submits that one of ordinary skill in the art could not write down all of these nearly 200 million sequences, and thus could not once envision instantly claimed SEQ ID NO: 15 from this huge genus.

Accordingly, Applicant submits that one of skill could not write down or analyze all of these sequences, and at once envision the instantly claimed SEQ ID NO: 15 from among. Therefore, the vast, nearly infinite genus of sequences disclosed by Tuschl cannot anticipate the instantly claimed subject matter of claims 32, 40, and 42. In view of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 32, 40, and 42 under 35 U.S.C. § 102(e).

3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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